

### **Remarks**

Please amend claim 126 such that the claimed peptide mimetic falls within the scope of the elected species. It was mistakenly stated by the Applicants in the response of Dec. 22, 2005 and affirmed by the Examiner in the present Office Action that the instant claim 126 is within the scope of the elected species. Support for this amendment is found, for example, in the Examples for the synthesis of compounds 74 and 75 on pages 40-41 of the Specification. As such, no new matter is added by way of this amendment.

### **Election / Restrictions**

Applicants respectfully traverse the refusal by the Examiner to examine claims 114-118, 122-123, 125, 127-133, 136, 139, and 141-144 as being drawn to a non-elected species on the grounds that there is no allowable generic or linking claim. Applicants submit that claim 113, a linking claim, is allowable as discussed below in that the rejections of claim 113 under 35 USC §102(b) and §103(a) are not proper. To the extent that the rejection of claim 113 is maintained, Applicants respectfully request reconsideration and withdrawal of the rejection of claim 113, and accordingly ask to Examiner to proceed to examine the unexamined claims noted above.

### **Priority**

Applicants request reinstatement of the previous acceptance of the priority document for the application, Australian patent PP2548, filed March 24, 1998. A response was filed by Applicants on Oct. 16, 2002 in response to the Office communication of Aug. 16, 2002 stating that the acceptance had been withdrawn, but this response was not acknowledged in the Office Action dated Feb. 21, 2003. Please reinstate the acceptance notice for this priority document and accord the application the proper filing date.

### **Claim Rejections - 35 USC §102**

Claims 113, 119, 120, 121, 124, 126, 134, 135, 137, 138, and 140 were rejected for lack of novelty over Ma *et al.*, 1995, *Peptide and Protein Letters*, 2, 347-350.

Applicants traverse the rejection and, to the extent it is maintained, request reconsideration and withdrawal of the rejection.

In the accompanying Declaration, submitted under 37 CFR §1.132, the Applicants herein provide extensive details of experimental work that refute the contention of Ma that synthesis of

Ma's compound 1 in Scheme 1 (page 349) was actually achieved. Rather, Ma achieved the synthesis of an isomeric structure that does not contain the 1,4-diazacycloheptane ring nucleus.

It has been held, and is still good law, that "before any publication can amount to a statutory bar to the grant of a patent, its disclosure must be such that a skilled artisan could take its teachings in combination with his own knowledge of the particular art and be in possession of the invention." *Application of Hoeksema*, 399 F.2d 269, 273 (C.C.P.A. 1968).

In that the synthesis disclosed by Ma does not in fact provide a method to put a compound of the present invention into the possession of the skilled artisan, Ma cannot properly be said to anticipate any of the rejected claims. Ma does not disclose any synthesis of a 1,4-diazacycloheptane structure, as shown by abundant spectroscopic evidence and literature precedent as discussed in the Declaration.

Therefore, Applicants respectfully request withdrawal of this rejection. If the Examiner decides to maintain this rejection, Applicants respectfully request that the Examiner telephone so that we may discuss this matter.

### **Claim Rejections - 35 USC §103**

Claims 113, 119, 120, 121, 124, 126, 134, 135, 137, 138, and 140 were rejected for obviousness over Gardner in view of Alkorta.

Applicants respectfully traverse the rejection and, to the extent it is maintained, request reconsideration and withdrawal of the rejection.

The applicants agree with the Examiner's characterization that the claimed invention is drawn to a protein  $\gamma$ -turn mimetic in which the hydrogen bond as shown in the Examiner's report is replaced by two methylene groups so as to form the 1,4-diazacycloheptane derivative shown in the report.

However, the Gardner paper describes the application of the patented Kahn generation 2 beta turn scaffold to enkephalin mimetics. It is correct that Gardner describes the preparation of a Gly-Phe-Leu product and use of this to prepare a turn mimetic. It is respectfully submitted however that this has no relevance to the present application which makes  $\gamma$ -turn mimetics. The present applicants note that the concept of making turn mimetics of enkephalin was not novel at

the time of Gardner's paper (the first example of the reduction to practice of this concept was Belanger P.C. Dufresne, C, Can.J.Chem 1986, 64, 1514 to 1520). Accordingly on its own the applicants do not believe that a skilled addressee on reading the Gardner paper would be lead to the completion of the present invention which relates to the formation of a different turn mimetic based on the Gly-Phe-Leu series. In other words the description of one turn mimetic dose not discloses all turn mimetics.

The applicants note that the Alkorta paper is a molecular modelling paper. It does not indeed teach the synthesis of any compound and merely provides molecular calculation on a number of turn mimetics of this system but generally in regard to quite common or simple systems. It is not clear if it is applicable to substituted systems such as the present.

Accordingly the applicants respectfully submit that it would not have been *prima facie* obvious to one of ordinary skill in the art of the claimed invention to submit the Gly-Phe-Leu sequence of Gardner to the simulation comprising the 1,4-diazacycloheptane turn mimetic of Alkorta. The applicants note that the Alkorta paper proposed a number of different potential mimetic systems without teaching the specific diazacycloheptane structure nor that it could be applied to anything other than simple mimetic systems as opposed to the complex mimetic structures of the present invention. The Alkorta paper also teaches away from use of the diazacycloheptane mimetic as several of the other mimetic systems examined gave better similarity scores to the ideal gamma turn – specifically compounds 7 and 11 always gave better similarity scores and compounds 2, 3, 5, 9, 13 and 14 regularly (being more than one time) gave similarity scores exceeding those of the diazacycloheptane. It is the applicants submission that based on Alkorta there are a number of different structures that could be used in the Alkorta modelling paper, and there is nothing in Alkorta that would lead a skilled artisan to necessarily select the diazacycloheptane mimetic system from the other systems described or to arrive at the Gly-Phe-Leu sequence of Gardner. Notwithstanding the fact the computational time would remain tractable there is nothing to suggest that the more complex molecules described in Gardner would in fact be amenable to the cyclizations of Alkorta especially in light of the fact that Gardner makes  $\beta$ -turn mimetics as opposed to the  $\gamma$ -turn mimetics of the present application.

Accordingly it is respectfully submitted that the rejection under USC 35 §103 is improper and applicants respectfully request its reconsideration and withdrawal.

**Conclusion**

Applicant respectfully submits that the claims are in condition for allowance and notification to that effect is earnestly requested. The Examiner is invited to telephone Applicant's attorney 612-373-6941 to facilitate prosecution of this application.

If necessary, please charge any additional fees or credit overpayment to Deposit Account No. 19-0743.

Respectfully submitted,

PETER JOSEPH CASSIDY, ET AL. and  
THE UNIVERSITY OF QUEENSLAND

By their Representatives,

SCHWEGMAN, LUNDBERG, WOESSNER & KLUTH, P.A.  
P.O. Box 2938  
Minneapolis, MN 55402  
612-373-6941

Date Sept. 26, 2006

By Geoffrey K. Cooper  
Geoffrey K. Cooper  
Reg. No. 51,266

**CERTIFICATE UNDER 37 CFR § 1.8:** The undersigned hereby certifies that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail, in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on this 26<sup>th</sup> day of September 2006.

Name: PATRICIA A. HULTMAN

Signature: [Signature]